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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PONNALURI, PADMASHRI

ART UNIT PAPER NUMBER

1639

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,734

Applicant(s)

SPITZER, A. ROBERT

Examiner

Padmashri Ponnaluri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 25 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-21, 28, 29, 31 and 32 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22, 25, 27 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The response filed on 10/11/05 has been fully considered and entered into the application.
2. Claims 1-22, 25, 27-32 are currently pending in this application.
3. Claims 1-21, 28-29, 31-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/28/05.
4. This application contains claims 1-21, 28-29, 31-32 are drawn to an invention nonelected without traverse in reply file don 3/28/05. A complete reply to the final rejection must include cancellation of nonelected claims.
5. Claims 23-24 and 26 have been canceled. Claims 22, 25, 27 and 30 are currently being examined in this application.

Priority

6. This application claims priority to provisional applications 60/264,413 filed on 1/26/01 and 60/302,799 filed on 7/3/01.

Withdrawn Claim Rejections

7. The rejection of claims 22, 25 and 27 under 35 U.S.C. 102(b) as being anticipated by US Patent 6,096,742 (Crocker et al) has been withdrawn in view of the amendments to claim 22.

Maintained Claim Rejections

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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9. The rejection of claims 22, 25, 27 under 35 U.S.C. 102(b) as being anticipated by US Patent 5,500,221 (Murata et al) has been maintained for the reasons of record.
10. The rejection of claims 22, 25, 27, and 30 under 35 U.S.C. 102(e) as being anticipated by US Patent 6,268,396 (B1) (Nau et al) has been maintained for the reasons of record.
11. The rejection of claims 22, 27 under 35 U.S.C. 102(b) as being anticipated by US Patent 4,369,172 (Schor et al) has been maintained for the reasons of record.

Response to Arguments

12. *Claims 22, 25, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,500,221 (Murata et al).*

The instant claims briefly recite a medicine suppository comprising an effective amount of medication selected from the group consisting of valproate, valproate salts and sodium valproate. NOTE the recitation 'for the treatment of a migraine headache' is considered as intended use.

Murata et al disclose suppository preparation comprising a therapeutically effective amount of an acidic drug or a pharmaceutically acceptable salt thereof which can be absorbed by rectal administration, wherein the acidic drug is sodium valproate (i.e., see claim 1) (reads on the instant claim medicine suppository comprising valproate. Murata et al teach that the suppository preparation contains other additives, such as absorption enhancers, preservatives, stabilizers, surfactants, perfumes, pigments, purified water, and various polymers (i.e., see column 3) (reads on the instant claim 27). The reference clearly anticipates the claimed invention.

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13. *Claims 22, 25, 27, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,268,396 (B1) (Nau et al).*

The instant claims briefly recite a medicine suppository comprising an effective amount of medication selected from the group consisting of valproate, valproate salts and sodium valproate. NOTE the recitation 'for the treatment of a migraine headache' is considered as intended use. Claim 30 recites a method of treating a migraine.

Nau et al teach a method for treatment and prevention of migraine and effective illness by administering a therapeutically effective amount of valproic acid analog 2-n-propyl-4-hexynoic acid (refers to instant claim valproate) (i.e., see abstract). The reference teaches that administration of the compounds of this invention may be by any method used for administering therapeutics, such as rectal administration. The reference teaches pharmaceutical composition for the treatment of migraine comprising the 2-n-propyl-4-hexynoic acid or salts thereof, additives, such as preservatives, excipients, fillers, wetting agents, binders, disintegrates, buffers, carriers (i.e., see column 4). The reference teaches that the compositions may be in the form of tablets, capsules, suppositories (refers to the instant claim suppository) (i.e., see column 4). The reference clearly anticipates the claimed inventions.

14. *Claims 22, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,369,172 (Schor et al).*

The instant claims briefly recite a medicine suppository comprising an effective amount

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of medication selected from the group consisting of valproate, valproate salts and sodium valproate. NOTE the recitation 'for the treatment of a migraine headache' is considered as intended use.

Schor et al teach a carrier base material combined with a therapeutically active medicament. The reference teaches that the active ingredient is a type of medication, which can be transmitted into the blood circulation through the rectal tissue (i.e., see column 5), and the medication includes drugs, which treat migraine headaches. The reference teaches the active medicament includes sodium valproate (i.e., see column 6). The reference teaches that for vaginal and rectal suppositories, the release pattern of the active medicament is predetermined (i.e., see column 8). The reference composition comprises carrier, solvents and additives. Thus, the reference clearly anticipates the claimed invention.

16. Applicant's arguments filed on 10/11/05, regarding the art rejections of claims over US Patent 5,500,221 (Murata); US Patent 6,268,396 (Nau et al); US Patent 6,096,742 (Crocker et al) have been fully considered but they are not persuasive.

It has been noted that applicants have argued all the three separate rejections together.

Applicant's response has not addressed the anticipatory rejection of claims over and US Patent 4,369,172 (Schor et al).

Applicants assert that the amendment to claim 22 'a medicine suppository consisting essentially of.' is closed language, thereby distinguishing over each of the cited references.

Applicant's arguments and assertions have been fully considered and are not persuasive for the following reasons.

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The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).

"A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. see MPEP 2111.03

Murata clearly discloses suppository preparation comprising sodium valproate (a drug) and an acidic compound or pH buffer. Murata et al clearly teaches that the drug is the essential component of the suppository, and the use of acidic compound is only enhancer or additive. Thus, the recitation of the transition phrase 'consisting essentially of' would not exclude the reference acidic compound or pH buffer.

Nau et al discloses valproate analogs in suppository composition for treatment of migraine headache.

Schor et al teach medications to treat migraine headaches, and the active medicament in the medication is sodium valproate, and rectal administration methods.

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Thus the references teach the limitations of the instant claims, and the rejections of record have been maintained.

Conclusion

17. No claims are allowed.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


PADMASHRI PONNALURI
PRIMARY EXAMINER

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

13 February 2006
~~04 April 2006~~